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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/589,841 | 07/05/2007 | Jun Nakayama | BURN1110-1 | 2798 |
| 28213 | 7590 | 11/13/2009 | EXAMINER | |
| DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133 | | | MONTANARI, DAVID A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/589,841 | NAKAYAMA ET AL. | |
| | Examiner | Art Unit | |
| | David Montanari | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 21-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/2/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-20 in the reply filed on 8/11/2009 is acknowledged.

Claims 21-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 8/11/2009.

Claim Objections

Claim 17 is objected to because of the following informalities: In line 1 the word "which" should be replaced with the word "further" to be grammatically correct. Appropriate correction is required.

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1632

Claims 1-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama et al. (1999, PNAS, Vol. 96, pgs. 8991-8996) as evidenced by Xing et al. (1989, Immunol. Cell Biol., Vol. 67, pgs. 183-195)

With respect to the limitation of “mucin-type” in claim 16 this is broadly interpreted to encompass any glycoprotein that has a high level of *O*-linked oligosaccharides, which is art accepted as the defining characteristic of “mucin-type” glycoproteins .

Claims 1-16 and 18-20 are drawn to a non-naturally occurring compound comprising at least one α 1,4-linked N-acetylglucosamine (α 1,4-linked GlcNAc) residue operatively linked to a carrier molecule, wherein said carrier molecule comprises a polypeptide, a *O*-glycan, a core 2 branched *O*-glycan, a mucin-like polypeptide such as leukosialin, wherein a plurality of α 1,4-linked GlcNAc residues exist on said compound and a method of producing a glycoprotein comprising at least one α 1,4-linked GlcNAc residue, wherein said glycoprotein is isolated.

Nakayama et al. teach the expression cloning of a cDNA encoding a human α 1,4-*N*-acetylglucosaminyltransferase (α 4GnT), which is a key enzyme for the formation of GlcNAc α 1 \rightarrow 4Gal β \rightarrow R (Abstract lines 9-12). Nakayama continues that “By using the cDNA isolated, we have established that α 4GnT forms GlcNAc α 1 \rightarrow 4Gal β \rightarrow R preferentially in core 2 branched oligosaccharides and that the transcripts of α 4GnT are predominantly expressed in the stomach and pancreas” (pg. 8991 col. 2 last 5 lines). Nakayama continues that their “results indicate that the α 4GnT is a glycosyltransferase that forms α 1,4-linked GlcNAc residues, preferentially in *O*-glycans” (Abstract last 3 lines).

Regarding claims 2, 4, 6, 8, 9, 11, 13-16, 18 and 20, Nakayama et al. teach a non-naturally occurring compound comprising at least one α 1,4-linked GlcNAc residue operatively

Art Unit: 1632

linked to a carrier molecule, wherein the carrier molecule comprises an *O*-glycan. Nakayama continues to teach that said compound was generated in COS-1 cells (pg. 8992 col. 1 parag. 1 lines 1-10). Nakayama continues to teach that leukosialin is a major membrane-bound sialoglycoprotein of leukocytes and contains 80 *O*-glycans in its extracellular domain (pg. 8995 col. 1 parag. 5 lines 14-16). Nakayama continues to teach that the co-transfected COS-1 cells expressed the claimed compound when GlcNAc α 1 \rightarrow 4Gal β \rightarrow R residues were expressed on the cell surface (pg. 8993 col. 1 parag. 2 bridge col. 2 parag. 1 lines 1-3 and Fig. 1) that were attached to the *O*-glycans of leukosialin (pg. 8993 col. 2 parag. 2).

Specifically regarding the method of claim 13 and its dependent claims 14 and 15 are further anticipated by the teachings of Nakayama. Claim 13 requires contacting α 4GnT and a carrier polypeptide to produce a glycoprotein. Nakayama continues to teach that leukosialin is a sialoglycoprotein and that the results reported on pg. 8993 demonstrated GlcNAc α 1 \rightarrow 4Gal β \rightarrow R residues bound to a *O*-glycan which is leukosialin, thus the method of claim 13 is anticipated by the teachings of Nakayama.

Specifically regarding the carrier polypeptide of claim 14, this will be soluble in some buffer or medium, though none is claimed or defined in the specification.

Specifically regarding claim 16, the leukosialin taught by Nakayama is a "mucin-type" glycoprotein which is naturally secreted in milk, as evidenced by Xing et al. who teach that mucin-type glycoproteins are a natural component of breast milk (Abstract and pg. 192 col. 2 parag. 2 lines 1-2)

Regarding claims 3, 5, 7, 10, 12 and 19, Nakayama teaches that a soluble α 4GnT fused with protein A was expressed and its activity was assayed by using a variety of synthetic

Art Unit: 1632

acceptors (pg. 8994 col. 1 parag. 4 lines 1-5). Nakayama continues to teach that α 1,4-linked GlcNAc residues were attached to a core 2 branched oligosaccharide (Gal β 1 \rightarrow 4GlcNAc β 1 \rightarrow 6(Gal β 1 \rightarrow 3)GalNAc α \rightarrow pNP), and a core 1 oligosaccharide(Gal β 1 \rightarrow 3GalNAc α \rightarrow pNP)(pg. 8994 col. 1 parag. 4 lines 5-10). Nakayama continues that to determine the structure of the oligosaccharide product comprising α 1,4-linked GlcNAc residues attached to the to core 2 branched oligosaccharide (Gal β 1 \rightarrow 4GlcNAc β 1 \rightarrow 6(Gal β 1 \rightarrow 3)GalNAc α \rightarrow pNP), an enzymatic reaction was performed by using 300 nmol of Gal β 1 \rightarrow 4GlcNAc β 1 \rightarrow 6(Gal β 1 \rightarrow 3)GalNAc α \rightarrow pNP as an acceptor and then isolated and subjected to NMR analysis with data reported in Table 1 (pg. 8994 col. 2 parag. 1 lines 1-4). Nakayama continues to teach in Fig. 5 a list of nine different acceptors incorporated by a soluble chimeric α 4GnT.

Thus the teachings of Nakayama clearly anticipate the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1632

Claim 7 recites the limitation "wherein the *O*-glycan" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation " wherein the *O*-glycan " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 is free of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/589,841

Page 7

Art Unit: 1632

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/Peter Paras, Jr./

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